DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

May 7, 2002

WARNING LETTER
CHI-18 -02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Anthony Costello, President
Optimum Nutrition, Inc.
600 N. Commerce St.
Aurora, IL 60504

Dear Mr. Costello:

The Food and Drug Administration (FDA) inspected your firm on July 25, 26 and 27, 2001. At that time, a sample of product labeled as stevia powder was collected for confirmation of identity by our Denver Laboratory. Labels and labeling of several of your firm's products, which you have stated contain stevia, were also collected. This letter is to advise you of the findings of our laboratory analysis, as well as of the relation of these findings to your use of stevia in several of your food products, and additionally of the findings of our review of your labeling. Labeling is not limited to the immediate product container but, as defined in Section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act), includes all promotional material you distribute in connection with your products.

Our laboratory has confirmed the identification of stevia in the sample we collected. You have already indicated to our investigator that the stevia we sampled is the same stevia which you use in the following food products that you manufacture, which are all labeled to contain stevia: Natural Opti-Soy 50, Natural PRO COMPLEX, and Natural 100% Egg Protein.

Stevia is considered a food additive when used as an ingredient in a conventional food. There is no regulation in effect that provides for the safe use of stevia, nor is there a sufficient basis to conclude that stevia is generally recognize as safe (GRAS) among qualified experts for its intended use in food. Therefore, stevia is an unapproved food additive that is unsafe under Section 409 of the Act. The presence of stevia in your products Natural Opti-Soy 50, Natural PRO COMPLEX, and Natural 100% Egg Protein renders these products adulterated under Section 402(a)(2)(C) of the Act.

We have also noted that the label for your Natural Opti-Soy 50, a soy protein product, states that soy protein "... may play a significant inhibitory role in certain cancers and atherosclerosis development." Your promotional literature for your soy product links soy use to slowing the development of atherosclerosis and heart disease. Since a health claim for the relationship between soy and diseases other than coronary heart disease has not been authorized by regulation or the Act, your Natural Opti-Soy 50 is misbranded under Section 403 (r)(1)(B) of the Act. It is misbranded since the claims that this product makes for inhibiting cancer and atherosclerosis are unauthorized health claims.

With respect to your claim about soy protein and heart disease, the soy health claim regulation (21 CFR 101.82) authorizes claims about soy protein and reduced risk of heart disease under certain conditions. However, your claim fails to meet the requirements of the regulation in several respects, including the fact that the claim does not specify the daily dietary intake level of soy protein associated with reduced risk (25g), or the amount of soy protein in a serving of your product. Additionally, a food must contain at least 6.25 grams of soy protein per serving to qualify for the soy health claim (see 21 CFR 101.82 (c)(2)(iii)(A)). It is not clear from the product label whether Natural Opti-Soy 50 qualifies to make a health claim about soy protein and heart disease, since the amount of soy protein per serving is not declared. Because your claim about soy protein and heart disease does not comply with the requirements of the authorizing regulation, that claim is an additional reason why Natural Opti-Soy 50 is misbranded under Section 403(r)(1)(B) of the Act.

Statements in the labeling for your Natural 100% Whey Protein Dietary Supplement claim that whey protein builds muscle mass, increases serotonin levels, and has other effects on the structure or function of the body. If these claims are statements made under Section 403(r)(6) of the Act, they must include the disclaimer required by that section. Requirements for the format and placement of the mandatory disclaimer are found in 21 CFR 101.93.

Further, your Natural 100% Whey Protein Dietary Supplement is misbranded because the label bears the statement "Very Low Lactose," a nutrient content claim that has not been defined by regulation. [Section 403 (r)(1)(A) of the Act and 21 CFR 101.13]

Additionally, your Natural 100% Whey Protein and your Natural Pro Complex are misbranded because the ingredient list on the product label includes terms that are not part of the usual name of the respective ingredients. These terms include "QuadPlex Protein Blend" for whey protein concentrate and isolate (Natural 100% Whey Protein),

and "Ultrafiltered" for whey protein concentrate (Natural 100% Whey Protein). Also, "Ion Exchange and Cross Flow Microfiltration" for whey protein isolate (Natural 100% Whey Protein and Natural Pro Complex), and "beta lactoglobulin, alpha lactalbumin, immunoglobulins, glycomacropeptides, lactoferrin, lactoperoxidase, other closely related protein molecules and glutamine peptides" for whey protein concentrate and isolate (Natural 100% Whey Protein). [Section 403 (i)(2) of the Act and 21 CFR 101.4].

In your label for your Natural Pro Complex and for your Natural 100% Egg Protein, the statement "APPROVED TO MANUFACTURE OVER THE COUNTER PHARMACEUTICALS" is false and misleading, since it implies that these products are subject to and comply with the manufacturing standards that apply to over-the-counter drugs.

The products Natural Opti-Soy 50, Natural Pro Complex and Natural 100% Egg Protein contain a "Supplement Facts" panel. However, these products are not labeled as dietary supplements, and therefore they do not meet the definition of a dietary supplement. [Section 201(ff)(2)(C) of the Act]. Rather, the products are foods that are required to bear a "Nutrition Facts" panel in the format prescribed by 21 CFR 101.9. Because the labels of these products do not include a "Nutrition Facts" panel, they are misbranded under Section 403(q) of the Act.

This letter is not intended to be an all-inclusive review of labels/labeling and products marketed by your firm. We note other labeling violations that we have not included in this letter. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions without further notice. These actions include seizure and/or obtaining a court injunction against further marketing of your products.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which corrections will be completed.

Your reply should be directed to James T. Karpus, Compliance Officer, at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director

cc: Mr. Luis Sanchez
Quality Control Manager
Optimum Nutrition, Inc.
600 N. Commerce St.
Aurora, IL 60504